K 103615

510(k) SUMMARY

SEP - 8 2011

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	
Date Summary Prepared:	Dec 7, 2010 [Date Updated: August 19, 2011]	
Device:	Trade Name:	ACE Urea Nitrogen Reagent
	Classification:	Class 2
	Common/Classification Name: Nitrogen	Urease, Photometric, Urea (21 C.F.R. § 862.1770) Product Code CDN
	Trade Name:	ACE Calcium-Arsenazo Reagent
	Classification:	Class 2
	Common/Classification Name:	Azo Dye, Calcium (21 C.F.R. § 862.1145) Product Code CJY
	Trade Name:	ACE Creatinine Reagent
	Classification:	Class 2
	Common/Classification Name:	Alkaline Picrate, Colorimetry, Creatinine (21 C.F.R. § 862.1225) Product Code CGX
	Trade Name: Reagent	ACE Inorganic Phosphorus U.V.
	Classification:	Class 1
	Common/Classification Name:	Phosphomolybdate (Colorimetric), Inorganic Phosphorus (21 C.F.R. § 862.1580) Product Code CEO

	Trade Name:	ACE Urine Standard
	Classification:	Class 2
	Common/Classification Name:	Calibrator, Multianalyte Mixture (21 C.F.R. § 862.1150) Product Code JIX
Predicate Devices:	Manufacturer for the reagent system predicate devices: Roche Diagnostics COBAS INTEGRA reagents: **Reagent** — **510(k)#** Urea/BUN — K954000 Calcium — K896224 Phosphate (Inorganic) ver.2 — K883962 Siemens Healthcare Diagnostics ADVIA 1800/2400 reagent: **Reagent** — **510(k)#** Creatinine (CRE_2c) — K901229 Verichem Laboratories, Inc. standard: **Reagent** — **510(k)#** Urine Chemistry Standard — K875285	
Device Descriptions:	In the ACE Urea Nitrogen Reagent assay, urea in urine is hydrolyzed to yield ammonia and carbon dioxide in the presence of urease. The ammonia formed then reacts with 2-oxoglutarate and NADH in the presence of glutamate dehydrogenase to yield glutamate and NAD. Two moles of NADH are oxidized for each mole of urea present. NADH absorbs strongly at 340 nm, whereas NAD^+ does not. The initial rate of decrease in absorbance, monitored bichromatically at 340 nm/647 nm, is proportional to the urea concentration in the urine sample. In the ACE Calcium-Arsenazo Reagent assay, calcium reacts with Arsenazo III in an acidic solution to form a blue-purple colored complex, which is measured bichromatically at 647 nm/692 nm. The intensity of color produced is directly proportional to the calcium concentration in the urine sample. In the ACE Creatinine Reagent assay, creatinine reacts with picric acid in an alkaline medium to form a red-orange colored complex, which absorbs strongly at 505 nm. The rate of complex formation, determined by measuring the increase in absorbance bichromatically at 505 nm/573 nm during a fixed time interval, is directly proportional to the creatinine concentration in the urine sample. In the ACE Inorganic Phosphorus U.V. Reagent assay, under acidic conditions, inorganic phosphorus reacts with ammonium molybdate to form an unreduced phosphomolybdate complex, which absorbs strongly at 340 nm. The increase in absorbance, measured	

	bichromatically at 340 nm/378 nm, is directly proportional to the amount of phosphorus in the urine sample. The ACE urine standard is a liquid, aqueous-based, ready-to-use calibration solution with known gravimetric concentrations of several analytes.
Intended Use:	Indications for Use: The ACE Urea Nitrogen Reagent is intended for the quantitative determination of urea nitrogen concentration in serum and urine using the ACE and ACE Alera Clinical Chemistry Systems. Urea nitrogen measurements are used in the diagnosis and treatment of certain renal and metabolic diseases. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The ACE Calcium-Arsenazo Reagent is intended for the quantitative determination of calcium in serum and urine using the ACE and ACE Alera Clinical Chemistry Systems. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The ACE Creatinine Reagent is intended for the quantitative determination of creatinine in serum and urine using the ACE and ACE Alera Clinical Chemistry Systems. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis and as a calculation basis for measuring other urine analytes. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The ACE Inorganic Phosphorus U.V. Reagent is intended for the quantitative determination of inorganic phosphorus concentration in serum and urine using the ACE and ACE Alera Clinical Chemistry Systems. Measurements of inorganic phosphorus are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases and vitamin D imbalance. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. Alfa Wassermann Diagnostic Technologies, LLC ACE Urine Standard is intended for the calibration of quantitative urine reagents on Alfa Wassermann Clinical Chemistry Systems. For *in vitro* diagnostic use only.

Technological Characteristics:	The ACE Urea Nitrogen Reagent consists of a single reagent bottle. The reagent contains α-ketoglutarate, urease, glutamate dehydrogenase, adenosine diphosphate (ADP), nicotinamide adenine dinucleotide and reduced (NADH). The ACE Calcium-Arsenazo Reagent consists of a single reagent bottle. The Reagent contains Arsenazo III. The ACE Creatinine Reagent consists of two reagent bottles (Sodium Hydroxide Reagent and Picric Acid Reagent). The Sodium Hydroxide Reagent (R1) contains sodium hydroxide. The Picric Acid Reagent (R2) contains picric acid. The ACE Inorganic Phosphorus U.V. Reagent consists of a single reagent bottle. The reagent contains ammonium molybdate and sulfuric acid. The ACE Urine Standard consists of a single dropper bottle. The standard contains known amounts of urea nitrogen, calcium, creatinine and phosphorus.
Performance Data:	Performance data for the Alfa Wassermann ACE reagents for urine testing included precision, accuracy and detection limit data. ACE Urea Nitrogen Reagent Precision: In testing conducted at five urea nitrogen levels for 22 days, on 2 different instruments, the within-run CV ranged from 1.1 to 2.3% and total CV ranged from 2.0 to 3.5%. In precision studies at three urea nitrogen levels at four separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.9 to 3.8% and total CV ranged from 1.6 to 4.6%. Accuracy: In one correlation study, 112 samples with urea nitrogen values ranging from 42 to 1883 mg/dL were assayed on the Alfa Wassermann ACE System (y) and the predicate method (x). Least squares regression analysis yielded a correlation coefficient of 0.9769, a standard error estimate of 71.1, a confidence interval slope of 0.871 to 0.945 and a confidence interval intercept of 7.9 to 68.9. In another correlation study, 112 samples with urea nitrogen values ranging from 48 to 1850 mg/dL were assayed on the Alfa Wassermann ACE Alera Clinical Chemistry System (y) and the predicate method (x). Least squares regression analysis yielded a correlation coefficient of 0.9805, a standard error estimate of 66.2, a confidence interval slope of 0.884 to 0.953, and a confidence interval intercept of -5.9 to 50.9. In patient correlation studies at four separate POL sites, using the Alfa Wassermann ACE reagents and the predicate device (x), least-squares regression analysis yielded correlation coefficients of 0.9853 to 0.9895, standard error estimates of 61.5 to 75.1, confidence interval slopes of 0.866 to 0.993, and confidence interval intercepts of -49.7 to 61.8.

	Detection limit: The detection limit was 10 mg/dL on the ACE and 14 mg/dL on the ACE Alera Clinical Chemistry Systems. ACE Calcium-Arsenazo Reagent Precision: In testing conducted at four calcium levels for 22 days, on 2 different instruments, the within-run CV ranged from 1.4 to 5.3% and total CV ranged from 1.6 to 5.7%. In precision studies at three calcium levels at four separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.8 to 6.9% and total CV ranged from 0.8 to 7.5%. Accuracy: In one correlation study, 108 samples with calcium values ranging from 1.1 to 28.8 mg/dL were assayed on the Alfa Wassermann ACE System (y) and the predicate method (x). Least squares regression analysis yielded a correlation coefficient of 0.9752, a standard error estimate of 1.35, a confidence interval slope of 0.973 to 1.060 and a confidence interval intercept of -0.37 to 0.76. In another correlation study, 109 samples with calcium values ranging from 1.0 to 28.8 mg/dL were assayed on the Alfa Wassermann ACE Alera Clinical Chemistry System (y) and the predicate method (x). Least squares regression analysis yielded a correlation coefficient of 0.9752, a standard error estimate of 1.37, a confidence interval slope of 0.979 to 1.066 and a confidence interval intercept of -0.46 to 0.66. In patient correlation studies at four separate POL sites, using the Alfa Wassermann ACE reagents and the predicate device (x), least-squares regression analysis yielded correlation coefficients of 0.9669 to 0.9810, standard error estimates of 1.35 to 1.70, confidence interval slopes of 0.935 to 1.125 and confidence interval intercepts of -1.64 to 1.24. Detection limit: The detection limit was 0.3 mg/dL on the ACE and 0.3 mg/dL on the ACE Alera Clinical Chemistry Systems. ACE Creatinine Reagent Precision: In testing conducted at five creatinine levels for 22 days, on 2 different instruments, the within-run CV ranged from 1.0 to 2.1% and total CV ranged from 2.6 to 3.3%. In precision studies at three creatinine levels at four separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.8 to 3.5% and total CV ranged from 1.5 to 5.8%. Accuracy: In one correlation study, 113 samples with creatinine values ranging from 8.2 to 308.7 mg/dL were assayed on the Alfa Wassermann ACE System (y) and the predicate method (x). Least squares regression analysis yielded a correlation coefficient of 0.9818, a standard error estimate of 11.40, a confidence interval slope of 0.950 to 1.021 and a confidence interval intercept of 2.62 to 10.92. In another correlation study, 113 samples with creatinine values ranging from 8.5

	to 329.1 mg/dL were assayed on the Alfa Wassermann ACE Alera Clinical Chemistry System (y) and the predicate method (x). Least squares regression analysis yielded a correlation coefficient of 0.9817, a standard error estimate of 11.95, a confidence interval slope of 0.992 to 1.066, and a confidence interval intercept of -3.25 to 5.44. In patient correlation studies at four separate POL sites, using the Alfa Wassermann ACE reagents and the predicate device (x), least-squares regression analysis yielded correlation coefficients of 0.9882 to 0.9904, standard error estimates of 10.72 to 12.24, confidence interval slopes of 0.928 to 1.101 and confidence interval intercepts of -6.84 to 9.66. Detection limit: The detection limit was 0.8 mg/dL on the ACE and 1.2 mg/dL on the ACE Alera Clinical Chemistry Systems. ACE Inorganic Phosphorus U.V. Reagent Precision: In testing conducted at five phosphorus levels for 22 days, on 2 different instruments, the within-run CV ranged from 0.7 to 2.2% and total CV ranged from 0.8 to 3.4%. In precision studies at three phosphorus levels at four separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.4 to 3.3% and total CV ranged from 0.6 to 4.6%. Accuracy: In one correlation study, 113 samples with phosphorus values ranging from 6.1 to 182.4 mg/dL were assayed on the Alfa Wassermann ACE System (y) and the predicate method (x). Least squares regression analysis yielded a correlation coefficient of 0.9878, a standard error estimate of 5.21, a confidence interval slope of 0.960 to 1.018 and a confidence interval intercept of 1.30 to 5.34. In another correlation study, 112 samples with phosphorus values ranging from 5.9 to 175.0 mg/dL were assayed on the Alfa Wassermann ACE Alera Clinical Chemistry System (y) and the predicate method (x). Least squares regression analysis yielded a correlation coefficient of 0.9886, a standard error estimate of 4.89, a confidence interval slope of 0.940 to 0.995 and a confidence interval intercept of 2.06 to 5.91. In patient correlation studies at four separate POL sites, using the Alfa Wassermann ACE reagents and the predicate device (x), least-squares regression analysis yielded correlation coefficients of 0.9809 to 0.9954, standard error estimates of 3.88 to 8.40, confidence interval slopes of 0.885 to 1.030 and confidence interval intercepts of -1.13 to 7.46. Detection limit: The detection limit was 1.6 mg/dL on the ACE and 1.2 mg/dL on the ACE Alera Clinical Chemistry Systems.
Conclusions:	Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Alfa Wasserman Diagnostic Technologies, LLC
c/o Hyman Katz, Ph.D.
Vice President, Quality and Regulatory Affairs
4 Henderson Drive
West Caldwell, NJ 07006

SEP - 8 2011

Re: k103615

Trade/Device Name: ACE Urea Nitrogen Reagent, ACE Calcium Arsenazo Reagent, ACE Creatinine Reagent, ACE Inorganic Phosphorus U.V. Reagent, ACE Urine Standard
Regulation Number: 21 CFR §862. 1770
Regulation Name: Urease, Photometric, Urea
Regulatory Class: Class II
Product Code: CDN, CJY, CGX, CEO, JIX
Dated: August 23, 2011
Received: August 24, 2011

Dear Dr. Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103615

Device Name: ACE Urea Nitrogen Reagent

Indications for Use: The ACE Urea Nitrogen Reagent is intended for the quantitative determination of urea nitrogen concentration in urine using the ACE and ACE Alera Clinical Chemistry Systems. Urea nitrogen measurements are used in the diagnosis and treatment of certain renal and metabolic diseases. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Device Name: ACE Calcium-Arsenazo Reagent

Indications for Use: The ACE Calcium-Arsenazo Reagent is intended for the quantitative determination of calcium in urine using the ACE and ACE Alera Clinical Chemistry Systems. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use X	AND/OR	Over-The-Counter Use
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 103615

Indications for Use

510(k) Number (if known): K103615

Device Name: ACE Creatinine Reagent

Indications for Use: The ACE Creatinine Reagent is intended for the quantitative determination of creatinine in urine using the ACE and ACE Alera Clinical Chemistry Systems. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis and as a calculation basis for measuring other urine analytes. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Device Name: ACE Inorganic Phosphorus U.V. Reagent

Indications for Use: The ACE Inorganic Phosphorus U.V. Reagent is intended for the quantitative determination of inorganic phosphorus concentration in urine using the ACE and ACE Alera Clinical Chemistry Systems. Measurements of inorganic phosphorus are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases and vitamin D imbalance. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Device Name: ACE Urine Standard

Indications for Use: Alfa Wassermann Diagnostic Technologies, LLC ACE Urine Standard is intended for the calibration of quantitative urine reagents on Alfa Wassermann Clinical Chemistry Systems. For *in vitro* diagnostic use only.

Prescription Use X	AND/OR	Over-The-Counter Use_
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103615